

SENATE RECORD VOTE ANALYSIS

104th Congress
1st Session

Vote No. 305

July 13, 1995, 5:30 p.m.
Page S-9874 Temp. Record

REGULATORY REFORM/Mammogram Regulations

SUBJECT: Comprehensive Regulatory Reform Act of 1995 . . . S. 343. Boxer amendment No. 1532 to the Dole/Johnston substitute amendment No. 1487.

ACTION: AMENDMENT AGREED TO, 99-0

SYNOPSIS: As reported, S. 343 will make changes to reform the regulatory process. The Dole/Johnston substitute amendment would modify the bill in accordance with suggestions made by Senate Democrats, the Administration, and the American Bar Association. The amendment would: recodify and modify the Administrative Procedures Act (APA); impose judicially reviewable obligations on Federal agencies to craft rules in which the benefits justify the costs and to use peer reviewed, standardized risk assessments; expand the Regulatory Flexibility Act; reform the Delaney Clause; and strengthen congressional oversight.

The Boxer amendment would exempt from this Act a final rule to implement the Mammography Quality Standards Act of 1992. NOTE: For related debate, see vote No. 304.

Those favoring the amendment contended:

The Food and Drug Administration (FDA) has recently announced that it is going to issue a final rule to implement the Mammography Quality Standards Act in October of this year. That rule may be derailed by this bill. Over the past few days we have heard very learned lawyers on both sides of this bill squabbling over its effects. These arguments are virtually unintelligible to those of us who are not lawyers, but one message has come through loud and clear--the effects of this bill are not that clear. Some of the best legal minds in the country are in the Senate. We think it is a sign of serious trouble when they cannot agree on the legal effect of a bill's language.

This proposed rule is extremely urgent. Women's lives are at stake. Every year, 46,000 women die of breast cancer. This amendment does not address a special interest; it addresses an enormous health problem that has touched or will touch virtually every American in their lifetime. Those Senators who think this amendment is about a narrow special interest would feel differently if it

(See other side)

YEAS (99)				NAYS (0)		NOT VOTING (1)	
Republican (54 or 100%)		Democrats (45 or 100%)		Republicans (0 or 0%)	Democrats (0 or 0%)	Republicans (0)	Democrats (1)
Abraham	Hutchison	Akaka	Inouye				Bingaman- ²
Ashcroft	Inhofe	Baucus	Johnston				
Bennett	Jeffords	Biden	Kennedy				
Bond	Kassebaum	Boxer	Kerrey				
Brown	Kempthorne	Bradley	Kerry				
Burns	Kyl	Breaux	Kohl				
Campbell	Lott	Bryan	Lautenberg				
Chafee	Lugar	Bumpers	Leahy				
Coats	Mack	Byrd	Levin				
Cochran	McCain	Conrad	Lieberman				
Cohen	McConnell	Daschle	Mikulski				
Coverdell	Murkowski	Dodd	Moseley-Braun				
Craig	Nickles	Dorgan	Moynihan				
D'Amato	Packwood	Exon	Murray				
DeWine	Pressler	Feingold	Nunn				
Dole	Roth	Feinstein	Pell				
Domenici	Santorum	Ford	Pryor				
Faircloth	Shelby	Glenn	Reid				
Frist	Simpson	Graham	Robb				
Gorton	Smith	Harkin	Rockefeller				
Gramm	Snowe	Heflin	Sarbanes				
Grams	Specter	Hollings	Simon				
Grassley	Stevens		Wellstone				
Gregg	Thomas						
Hatch	Thompson						
Hatfield	Thurmond						
Helms	Warner						

EXPLANATION OF ABSENCE:

- 1—Official Business
- 2—Necessarily Absent
- 3—Illness
- 4—Other

SYMBOLS:

- AY—Announced Yea
- AN—Announced Nay
- PY—Paired Yea
- PN—Paired Nay

were their wives who had breast cancer. If it were their wives, they would not be telling us that we do not need to worry because this bill already has an exemption; they would not be telling us that we have an interim final rule that is working just fine; they instead would be on the floor with us demanding the passage of the Boxer amendment. The Boxer amendment is simple, clear, and unmistakable in its message: the final rule on implementing the Mammography Standards Act will be exempt from this Act. This amendment is very important, because it reduces the debate to real terms of human suffering. When one gets right down to it, this bill is mostly about making it impossible for Federal regulators to stop greedy, immoral corporations from putting profits ahead of human health and the environment. This bill should be called the "Polluters and Poisoners Protection Act." The only ones who would benefit from defeating the Boxer amendment would be those disreputable health care providers who would rather use cheap, defective equipment, and hire cheap, incompetent help than give accurate breast exams. Sure, more women would suffer agonizing deaths, but they would make more money. We oppose letting women needlessly suffer and die, so we support the Boxer amendment.

While favoring the amendment, some Senators expressed the following reservations:

Our votes on this amendment should not in any way be misconstrued to be that we believe that it has any merit whatsoever. We are only voting in its favor to reassure the American people that Congress is serious about fighting breast cancer. If we voted against the amendment at this point, people would be unnecessarily alarmed into thinking that mammography standards were inadequate.

If the Boxer amendment is agreed to, the MQSA will be about the only area of public health for which we do not require that its guiding regulations be based on the best science possible. Thus, paradoxically, in order to quell alarm that we are not lowering the quality of breast exams, we are being forced to vote for an amendment that will result in a lower standard for regulating those exams. Overall, though, we are pleased with the way that the regulations have been working in practice for the past year and a half, so we do not expect great difficulties to ensue from granting this exemption, either as it applies to the interim rule or as it applies to whatever minor changes may be made for a final rule.

As we said at the outset, there is no practical need for the Boxer amendment. First, the EPA responds to emergencies primarily through enforcement actions, not rules, and those actions are exempt from this bill. Second, the bill applies to rules that cost over \$100 million, not to rules like the MQSA rule which we believe will really only cost \$33 million annually. Third, even assuming that this rule will have an annual cost in excess of \$100 million, we have no reason to believe it will not be ready for implementation on schedule under this bill's requirements, because the FDA has told us that it is treating it as a major rule by conducting cost-benefit analyses and risk assessments. Fourth, even if that treatment does not comply with one or two minor requirements in the Dole/Johnston substitute amendment, the analyses will still count as meeting all requirements because of a Johnston amendment we earlier adopted. Fifth, even if the MQSA rule did not qualify under the Johnston amendment, it would still be possible to implement it under this bill's exemption language for rules on health threats. That language, as amended by the Johnston language, would make that rule free from challenge for 1 year. After that year, one could challenge it on the basis that there is substantial evidence that it does not meet the risk assessment or cost benefit provisions of this bill. If that challenge were to succeed, the rule would not be thrown out--it would be fixed. What in the world is wrong with setting up a process that allows rules to be quickly put into effect before they are examined in order to be able to respond quickly, and then, after the fact, to examine the rules carefully, using the best science possible, to find out what changes need to be made to correct errors that were made in haste?

In a final note, the sponsor of the Boxer amendment, and many of the Senators who have spoken in its favor, also happen to be cosponsors of the proposed Glenn/Chafee substitute amendment that will soon be offered to the Dole/Johnston substitute amendment. These Senators, who have gone on about how they find the exemption language in the Dole/Johnston amendment inadequate, never mention that their proposed substitute does not have any exemption language. Rules in the works already will be allowed to slide by their substitute amendment, but rules in the future that are proposed to address health emergencies will receive no special treatment. For example, if next year a new health threat arises that causes ovarian cancer, and if the FDA wishes to issue a rule quickly to contain that threat, the Glenn/Chafee amendment would not allow it to do so. An existing Administrative Procedures Act waiver could be gained for the notice-and-comment period, which takes at most 60 days, but no waiver could be gained for the much longer period it takes to do a cost-benefit analysis, which is required by the Glenn/Chafee substitute amendment. Our point is that those Senators who on amendment after amendment have accused us of supporting a measure that will delay the implementation of needed regulations on health are totally, absolutely wrong, but if they were to look in the mirror and accuse themselves they would be right on target.

In the final analysis, the Boxer amendment is not needed for any practical purpose, and will in fact prove mildly harmful to the enactment of effective MQSA regulations. However, we still intend to vote in favor of the amendment in order to reassure those Americans who have been falsely led to believe that without the Boxer amendment this bill will put the lives of women at risk. The benefit of reassuring Americans outweighs the negative practical effects of the Boxer amendment, so we urge our colleagues to vote in its favor.